



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|----------------------------------|------------------------|
| 10/540,903 | 01/20/2006 | David W. Morris | PP023369.0003 | 3389 |
| 55255 7590 05/30/2007 SAGRES DISCOVERY INC. INTELLECTUAL PROPERTY - R440 P.O. BOX 8097 EMERYVILLE, CA 94662-8097 | | | EXAMINER STRZELECKA, TERESA E | |
| | | | ART UNIT 1637 | PAPER NUMBER |
| | | | MAIL DATE 05/30/2007 | DELIVERY MODE PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 10/540,903 | Applicant(s) MORRIS ET AL. | |
| | Examiner Teresa E. Strzelecka | Art Unit 1637 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-78 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Groups 1-13, claim(s) 1-15, 27, 28, drawn to an isolated nucleic acid comprising at least 10 contiguous nucleotides of a sequence selected from the group consisting of the polynucleotide sequences hR U-001 through hR U-013 shown in Tables 1-13, or its complement, classified in class 536, subclass 23.1, for example.

Group 1 corresponds to sequence hR U-001, Group 2 to sequence hRU-002, etc.
 - II. Groups 14-26, claim(s) 16-20, drawn to an isolated polypeptide, encoded within an open reading frame of a CA sequence selected from the group consisting of the polynucleotide sequences hD U-001 through hD U-013 shown in Tables 1-13, or its complement, classified in class 530, subclass 350, for example.

Group 14 corresponds to sequence hD U-001, Group 15 to sequence hDU-002, etc.
 - III. Group 27-39, claim(s) 21-26 and 60-75, drawn to an isolated antibody or antigen binding fragment thereof, that binds to a polypeptide according to anyone of claims 16-20, classified in class 530, subclass 387.1, for example.

Group 27 corresponds to sequence hD U-001, Group 28 to sequence hDU-002, etc.
 - IV. Group 40-52, claim(s) 29-31, drawn to an electronic library comprising a polynucleotide, or fragment thereof, comprising a CA polynucleotide sequence selected from the group consisting of the polynucleotide sequences hD U-001 through hD U-013 shown in Tables 1-13, classified in class 702, subclass 20, for example.

Group 40 corresponds to sequence hD U-001, Group 41 to sequence hDU-002, etc.

V. Group 53-65, claim(s) 32-39, drawn to a method of screening for anticancer activity of a drug candidate comprising:

(a) providing a cell that expresses a cancer associated (CA) gene encoded by a nucleic acid sequence selected from the group consisting of the sequences hD U-001 through hD U-013 shown in Tables 1-13 or fragment thereof;

(b) contacting a tissue sample derived from a cancer cell with an anticancer drug candidate; and (c) monitoring an effect of the anticancer drug candidate on an expression of the CA polynucleotide in the tissue sample, classified in class 435, subclass 6, for example.

Group 53 corresponds to sequence hD U-001, Group 54 to sequence hDU-002, etc.

VI. Group 66-78, claim(s) 40, 41, drawn to a method for detecting cancer associated with expression of a polypeptide in a test cell sample, comprising the steps of:

(i) detecting a level of expression of at least one polypeptide selected from the group consisting of hP U-001 through hP U-013 according to Tables 1-13, or a fragment thereof; and (ii) comparing the level of expression of the polypeptide in the test sample with a level of expression of polypeptide in a normal cell sample, wherein an altered level of expression of the polypeptide in the test cell sample relative to the level of polypeptide expression in the normal cell sample is indicative of the presence of cancer in the test cell sample, classified in class 435, subclass 7.1, for example.

Group 66 corresponds to sequence hP U-001, Group 67 to sequence hP U-002, etc.

VII. Group 79-91, claim(s) 42, drawn to a method for detecting cancer associated with expression of a polypeptide in a test cell sample, comprising the steps of:

- (i) detecting a level of activity of at least one polypeptide selected from the group consisting of hP-7-001 through hP U-013 according to Tables 1-13, or a fragment thereof wherein said activity corresponds to at least one activity for the polypeptide listed in Table 15; and
- (ii) comparing the level of activity of the polypeptide in the test sample with a level of activity of polypeptide in a normal cell sample, wherein an altered level of activity of the polypeptide in the test cell sample relative to the level of polypeptide activity in the normal cell sample is indicative of the presence of cancer in the test cell sample, classified in class 436, subclass 501, for example.

Group 79 corresponds to sequence hP U-001, Group 80 to sequence hP U-002, etc.

VIII. Group 92-104, claim(s) 43, drawn to a method for detecting cancer associated with the presence of an antibody in a test serum sample, comprising the steps of:

- (i) detecting a level of an antibody against an antigenic polypeptide selected from the group consisting of hP U-001 through hP U-013 according to Tables 1-13, or antigenic fragment thereof; and
- (ii) comparing said level of said antibody in the test sample with a level of said antibody in the control sample, wherein an altered level of antibody in said test sample relative to the level of antibody in the control sample is indicative of the presence of cancer in the test serum sample, classified in class 436, subclass 512, for example.

Group 92 corresponds to sequence hP U-001, Group 93 to sequence hP U-002, etc.

Art Unit: 1637

IX. Group 105-117, claim(s) 44-51, drawn to a method for screening for a bioactive agent capable of modulating the activity of a CA protein (CAP), wherein said CAP is encoded by a nucleic acid comprising a nucleic acid sequence selected from the group consisting of the polynucleotide sequences hR U-001 through hR U-013 shown in Tables 1-13, said method comprising:

- a) combining said CAP and a candidate bioactive agent; and
- b) determining the effect of the candidate agent on the bioactivity of said CAP, classified in class 435, subclass 7.1, for example.

Group 105 corresponds to sequence hR U-001, Group 106 to sequence hR U-002, etc.

X. Group 118-130, claim(s) 52, 53, drawn to a method for diagnosing cancer comprising:

- a) determining the expression of one or more genes comprising a nucleic acid sequence selected from the group consisting of the sequences outlined in Tables 1-13, in a first tissue type of a first individual; and
 - b) comparing said expression of said gene(s) from a second normal tissue type from said first individual or a second unaffected individual;
- wherein a difference in said expression indicates that the first individual has cancer, classified in class 436, subclass 64, for example.

Group 118 corresponds to sequence hP U-001, Group 119 to sequence hP U-002, etc.

XI. Group 131-143, claim(s) 54-59, drawn to a method for treating cancers comprising administering to a patient an inhibitor of a CA protein (CA.P), wherein said CAP is encoded

Art Unit: 1637

by a nucleic acid comprising a nucleic acid sequence selected from the group consisting of the sequences outlined in Tables 1-13, classified in class 514, subclass 1, for example.

Group 131 corresponds to sequence hP U-001, Group 132 to sequence hP U-002, etc.

XII. Group 144-156, claim(s) 76, drawn to a method for detecting a presence or an absence of cancer cells in an individual, the method comprising:

contacting cells from the individual with the antibody according to any of claims 60 or 61;

and detecting a complex of a CAP from the cancer cells and the antibody,

wherein detection of the complex correlates with the presence of cancer cells in the individual, classified in class 436, subclass 63, for example.

Group 144 corresponds to sequence hP U-001, Group 145 to sequence hP U-002, etc.

XIII. Group 157-169, claim(s) 77 and 78, drawn to a method for inhibiting growth of cancer cells in an individual, the method comprising: administering to the individual an effective amount of a pharmaceutical composition according to any of claims 71, 72, or 73, classified in class 530, subclass 388.1, for example.

Group 157 corresponds to sequence hP U-001, Group 158 to sequence hP U-002, etc.

2. The inventions are distinct, each from the other because of the following reasons:
3. Inventions (1-13) and (14-26) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The polypeptide of group (14-26) and polynucleotide of group (1-13) are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group (1-13) does not necessarily encode a polypeptide of group (14-26) since, for example, the nucleic acid molecule of claim 1 requires only 10 or more nucleotides (which would encode at most a polypeptide of 3 amino acids in length). Furthermore, the information provided by the polynucleotide of group (1-13) can be used to make a materially different polypeptide than that of group (14-26). For example, a nucleic acid which contains only 10 nucleotides of a polynucleotide with SEQ ID NO: 5, for example, encodes a protein that lacks any significant structure in common with a polypeptide encoded by SEQ ID NO: 5. In addition, while a polypeptide of group (14-26) can be made by methods using some, but not all, of the polynucleotides that fall within the scope of group (1-13), it can also be recovered from a natural source using biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of groups (1-13) and (14-26) are patentably distinct.

Furthermore, searching the inventions of groups (1-13) and (14-26) together would impose a serious search burden. In the instant case, the search of the polypeptides and the polynucleotides are not coextensive. The inventions of Groups (1-13) and (14-26) have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence

of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive.

The scope of polynucleotides as claimed extend beyond the polynucleotide that encodes the claimed polypeptides as explained above; furthermore, a search of the nucleic acid molecules of claim 1 would require an oligonucleotide search, which is not likely to result in relevant art with respect to the polypeptide of group (14-26). As such, it would be burdensome to search the inventions of groups (1-13) and (14-26) together.

4. Inventions (1-13) and (27-39) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The polynucleotide of group (1-13) and the antibody of group (27-39) are patentably distinct for the following reasons. The antibody of group (27-39) includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of group (27-39) which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of group (1-13) will not encode an antibody of group (27-39). Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching the inventions of group (1-13) and group (27-39) would impose a serious search burden since a search of the polynucleotide of group (1-13) is would not be used to determine the patentability of an antibody of group (27-39), and vice-versa.

5. Inventions (14-26) and (27-39) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The polypeptide of group (14-26) and the antibody of group (27-39) are patentably distinct for the following reasons:

While the inventions of both group (14-26) and group (27-39) are polypeptides, in this instance the polypeptide of group (14-26) is a single chain molecule that functions as an enzyme, whereas the polypeptide of group (27-39) encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the polypeptide of group (14-26) and the antibody of group (27-39) are structurally distinct molecules; any relationship between a polypeptide of group (14-26) and an antibody of group (27-39) is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, the polypeptide of group (14-26) is a large molecule which contains potentially hundreds of regions to which an antibody may bind, whereas the antibody of group (27-39) is defined in terms of its binding specificity to a small structure within the polypeptide. Thus immunization with the polypeptides of group (14-26) would result in the production of antibodies outside the scope of group (27-39). Furthermore, an antibody of group (27-39) would not

specifically bind all of the polypeptides of group (14-26). Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of group (14-26) and group (27-39) would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group (27-39). Furthermore, antibodies which bind to an epitope of a polypeptide of group (14-26) may be known even if a polypeptide of group (14-26) is novel. In addition, the technical literature search for the polypeptide of group (14-26) and the antibody of group (27-39) are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

6. Inventions (1-52) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The invention of Group (40-52) comprises an electronic library of polynucleotide fragments, and, as such, has no relationship to the existence of isolated polynucleotides, as the fragments could have been generated entirely in silico. Further, the data comprising polynucleotide sequences has no relationship to isolated polypeptides or antibodies. Therefore, search for a database containing the polynucleotide sequences does not guarantee that the actual polynucleotides exist, and does not reveal the existence of polypeptides or antibodies, making the searches divergent.

7. Inventions (1-13) and (53-65 and 118-130) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the

Art Unit: 1637

process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotides of Group (1-13) can be used to design an oligonucleotide array, rather than in the methods of Groups (53-65) and (118-130).

Searching the inventions of Groups (1-13) and (53-65 and 118-130) together would impose serious search burden. The inventions of Groups (1-13) and (53-65 and 118-130) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polynucleotides and the method of screening for anticancer drug activity or diagnosing cancer using a polynucleotide are not coextensive. Group (1-13) encompasses molecules which are claimed in terms of polynucleotide fragments, which are not required for the search of Groups (53-65) and (118-130). In contrast, the search for group (53-65) would require a text search for the method of screening for anticancer drug activity, and the search for Group (118-130) would require a text search for the method of cancer diagnosis using gene expression profiles. Prior art which teaches a polynucleotide that comprises 10 nucleotides of SEQ ID No: 5 would not necessarily be applicable to the method of using the polynucleotides. Moreover, even if the polynucleotide product were known, the method of diagnosis using the product may be novel and unobvious in view of the preamble or active steps.

8. Inventions (1-13) and (66-117 and 131-169) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polynucleotides of Group (1-13) are not required for the methods of Groups (66-117) and 131-169).

Art Unit: 1637

9. Inventions (14-26) and (53-65, 92-104 and 118-169) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptides of Group (14-26) are not required for the methods of Groups (53-65), (92-104) and (118-169).

10. Inventions (14-26) and (66-91 and 105-117) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Group (14-26) can be used in entirely different method, such as production of antibodies, rather than in the methods of Groups (66-91 and 105-117).

Searching the inventions of Groups (14-26) and (66-91 and 105-117) together would impose serious search burden. The inventions of Groups (14-26) and (66-91 and 105-117) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the polypeptides and the method of treating autoimmune disease using a polypeptide are not coextensive. The search for Groups 66-91 and 105-117 would require a text search for the method of detecting levels of polypeptide expression, a method of detecting cancer by detecting polypeptide activity or a method of screening for a bioactive agent capable of modulating protein activity. Prior art which teaches a polypeptide would not necessarily be applicable to the method of using the polypeptide. Moreover, even if the polypeptide product were known, the method of treatment which uses the product may be novel and unobvious in view of the preamble or active steps.

Art Unit: 1637

11. Inventions (27-39) and (53-91 and 105-143) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the antibodies of Group (27-39) are not required for the methods of Groups (53-91 and 105-143).

12. Inventions (27-39) and (92-104 and 144-169) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies of Group (27-39) can be used in an entirely different method, such as polypeptide detection, rather than in the methods of Groups (92-104 and 144-169).

Searching the inventions of Groups (27-39) and (92-104 and 144-169) together would impose serious search burden. The inventions of Groups (27-39) and (92-104 and 144-169) have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the search for the antibodies and the methods detecting cancer or inhibiting cancer cell growth using an antibody are not coextensive. The search for Groups (92-104, 144-156 or 157-169) would require a text search for the method of diagnosing cancer or inhibiting cancer cell growth. Prior art which teaches an antibody that binds to a polypeptide would not necessarily be applicable to the method of using the antibody. Moreover, even if the antibody product were known, the method of diagnosis which uses the product may be novel and unobvious in view of the preamble or active steps.

13. Inventions (40-52) and (53-169) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the electronic polynucleotide database of Group (40-52) is not required for the methods of Groups (53-169).

14. Inventions (53-169) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to methods with different method steps, starting materials and goals.

The instant specification does not disclose that these methods would be used together. For example, the method of screening for anticancer activity of a drug candidate (group 53-65), the method of detecting cancer using a polypeptide (group 66-78), and the method of detecting cancer using an antibody (group 79-91) are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs this function using a structurally and functionally divergent material. Moreover, the methodology and materials differ significantly for each of the methods. For screening of anticancer drug activity using the polynucleotide, hybridization may be used. For cancer detection using polypeptide expression, fluorescent cell counting may be used. For diagnosis using the antibody, quantitation of labeled antibody may be used. Therefore, each method is divergent in materials and steps. For these reasons the Inventions (53-169) are patentably distinct. Furthermore, the distinct steps and products require separate and distinct searches. The inventions of Groups (53-169) have a separate status in the art as shown by their different classifications. As such, it would be burdensome to search the inventions of Groups (53-169) together.

15. Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

16. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.**

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended

Art Unit: 1637

during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

17. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

18. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1637

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637

Teresa Strzelecka
5124107